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REMARKS

A. Status of the Claims

Claims 1, 15, 29, 30, and 32 have been amended to more clearly claim the Applicants' invention. Support for the amendment may be found in the Specification, for instance at page 10, lines 9-16, and in Tables 2 and 24. Claim 8 has been amended as suggested by the Action, in view of an informality. No new matter is added by the amendment. Claims 1-32 are currently pending and presented for reconsideration.

B. Claim Objection

The Official Action objects to claim 8 for use of the term "derived". Claim 8 has been amended as suggested, and Applicants respectfully submit that the objection is now moot.

C. Claim Rejection Under 35 U.S.C. § 112, First Paragraph – Written Description

The Action rejects claims 1-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, it is asserted that the specification fails to provide an adequate description of the genus of soybean plants that are agronomically elite and have a mean whole seed total protein content between 44-50%, a mean whole seed total protein plus oil content of between 64-70%, and a commercially significant yield, as well as parts thereof and methods of use, in terms of their genetic, morphological, and/or physiological characteristics.

Applicants initially note in response that the claims have been amended. The claimed characteristics relate to soybean varieties demonstrating (1) agronomically elite characteristics; (2) mean whole seed total protein content of between 45-50%; (3) mean whole seed total protein plus oil content of between 64-70%; (4) mean whole seed total oil content of at least 20%; and (5) commercially significant yield. This subject matter is fully described in the Specification in compliance with § 112, first paragraph. For example, "agronomically elite" is defined at page

38, lines 8-11, of the Specification, and includes distinguishing traits such as emergence, vigor, disease resistance, seed set, standability, and threshability, among others. This definition is well known in the art. The meaning of the terms "mean whole seed total protein content of between 45-50%"; "mean whole seed total protein plus oil content of between 66% and 70%"; and "mean whole seed total oil content of at least 20%" would be clear on their face to one of ordinary skill in the art. The term "commercially significant yield" is explicitly defined in the Specification at page 38, lines 19-21, as an actual grain yield of at least 35 bushels per acre as a mean measured over at least 15 environments.

Applicants respectfully submit that the Specification explicitly provides multiple examples demonstrating that the Applicants were in possession of this subject matter at the time of filing. For instance, in Example 1, soybean variety 0007583 is shown to have been selected based on agronomically elite criteria including seed yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity plant height, and seed oil and protein content, among others (Specification, page 44, lines 5-7; page 45, lines 2-4; page 49, lines 18-20). Variety 0007583 is further described as possessing a protein content of 46.2% (e.g. Table 2, Table 7), although some variability was seen. An oil content of 20.4% (e.g. Table 2, Table 7), is described, leading to an oil + protein content of 66.6%. Yield of 007583 is reported as 54.7 bu/ac in Table 7.

In Example 5, soybean variety 0137441 was selected based on agronomic characteristics including yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity, plant height, and seed oil and protein content (Specification, page 57, lines 17-19). Variety 0137441 is further described as possessing a protein content of 45.4% and an oil content of 20.4%, leading

to an oil + protein content of 65.8% (Table 24 at page 59). Yield of 00137441 is reported as 45.2 bu/ac in Table 24.

Based on the working examples, one of skill in the art could also generate new varieties using the same protocols described therein. For example, variety 0007583 was created by initially crossing lines A2553 and SN30003, as described in Example 1, and progeny were selected based on several listed agronomic criteria in conjunction with yield, protein, and oil content. Additionally, the described varieties, for instance 0007583 or 0137441 could themselves be used as parents in following the protocols of the working examples. Thus, Applicants have demonstrated possession of multiple soybean varieties displaying the claimed attributes.

Applicants therefore respectfully submit that, upon testing a given elite soybean variety for agronomic characteristics, yield and for protein and oil content in accordance with well known protocols, one of ordinary skill in the art should be able to "recognize the identity of members of the [claimed] genus" (*Univ. Calif. v. Eli Lilly*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). Applicants note that the Written Description Requirement must be analyzed with respect to the claimed invention, and not to unclaimed characteristics envisioned in the action. Thus, regarding any other (unclaimed) genetic, morphological, or physiological characteristics, Applicants submit that the rejection is mistaken, and its removal is respectfully requested.

D. Claim Rejection Under 35 U.S.C. § 112, First Paragraph- Enablement

(1) The Action rejects claims 15 and 30-32 as failing to comply with the enablement requirement, in that representative seed of soybean variety SN30003 is not available. In response, Applicants note that the specification, at page 43, lines 22-25, explains that such seed

is available to the public from the USDA National Soybean Germplasm Collection as PI599584.

The seeds are therefore well known and readily available and a deposit is not required under 37 C.F.R. 1.802.

(2) The Action also rejects claims 1-29 and 32 under 35 U.S.C. § 112 based on the assertion that the specification does not reasonably provide enablement for any and every agronomically elite soybean plant having the claimed mean whole seed protein content and mean whole seed total protein plus oil content, and a commercially significant yield. The Action further states, in view of the considerations of *in re Wands*, that undue experimentation would be necessary to practice the invention.

In response, Applicants note initially that the claims have been amended herein to recite soybean plants displaying a mean whole seed total protein content between 45-50%, a mean whole seed total protein plus oil content of between 64-70%, a mean whole seed total oil content of at least 20%, and a commercially significant yield, as well as tissue cultures and methods for developing them. The Specification provides sufficient disclosure to satisfy the enablement requirement of 35 U.S.C. § 112, First Paragraph, for this subject matter, in that the Specification provides working examples within the scope of the claims, and the knowledge of one of ordinary skill in the art provides sufficient guidance to practice the invention without undue experimentation.

For instance, in Example 1, soybean variety 0007583 is identified, derived from an initial cross of varieties A2553 and SN30003, and selected based on agronomically elite criteria including seed yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity plant height, and seed oil and protein content, among others (e.g. Specification, page 44, lines 5-7; page 49, lines 18-20; page 45, lines 2-4). Variety 0007583 is further described as possessing a

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protein content of 46.2% (Tables 2, 7), although some variability is noted. An oil content of 20.4% (e.g. Table 2, Table 7) is described, leading to an oil + protein content of 66.6%. Yield of 007583 is reported as 54.7 bu/ac in Table 7.

In Example 5, soybean variety 0137441 is identified, based on an initial cross of soybean varieties SN30003 and AG3302, and selected based on agronomic characteristics including yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity, plant height, and seed oil and protein content (Specification, page 57, lines 17-19). Variety 0137441 is further described as possessing a protein content of 45.4% and an oil content of 20.4%, leading to an oil + protein content of 65.8% (Table 24 at page 59). Yield of 00137441 is reported as 45.2 bu/ac in Table 24. Each of these characteristics may be determined by routine experimentation. Thus, working examples of the invention are provided. Although the action asserts that it would require undue trial and error experimentation for one skilled in the art to make and use the invention because one would have to screen literally thousands of soybean plants to determine which, if any, when crossed by a claimed parent would produce soybean plants in accordance with the claims, such a level of experimentation is routine in the plant breeding art, and is well within the skill of an ordinary practitioner.

One of skill in the art could also utilize the protocols described in the working examples to generate new varieties, using the same protocols described in the working examples. For example, variety 0007583 was created by initially crossing lines A2553 and SN30003, as described in Example 1, and progeny were selected based on several listed agronomic criteria in conjunction with yield, protein, and oil content. Additionally, the described varieties, for instance 0007583 or 0137441 could themselves be used as parents in following the protocols of the working examples.

The Specification contains extensive guidance on breeding methods (e.g. page 12, line 21, to page 25, line 5). The Specification also provides guidance as to how such measurements may be made, for instance by testing candidate soybean plants for yield, oil, and protein content, as well as for agronomic characteristics, all of which may be readily evaluated by one of skill in the art. Although the Action asserts that other genetic, morphological, and/or physiological characteristics are not provided, Applicants note that such characteristics, whatever they may be, are not being claimed, and are not relevant to the claimed invention. In contrast, the characteristics recited in the claims are readily understood.

Applicants also submit that Cober *et al.* (*Crop Sci* 40:39-42, 2000), cited by the Action, and Wilcox & Cavins (*Crop Sci*. 35:1036-1041, 1995), cited in the Action and also submitted as Reference C42 in the Information Disclosure Statement of November 29, 2004, as well as numerous references described in the Specification, for instance at page 3, lines 1-24, explicitly note that development of high yielding, high protein, and high total protein + oil soybean cultivars is difficult because of tight negative correlations between various of these phenotypes (e.g. as cited in Wilcox and Cavins at p. 1036, right column, top paragraph). The present application however teaches that it is possible, in contrast with teachings of the prior art, to achieve the claimed yield, protein, and oil characteristics in a soybean variety that also displays elite characteristics. The soybean varieties described in the Examples represent particular embodiments of the invention, and demonstrate the feasibility of the breeding strategy. Thus Applicants respectfully submit that the claimed subject matter is fully enabled in view of § 112, and respectfully request removal of this rejection.

(3) Claims 10-14 are also rejected in that the specification is alleged to not provide guidance with regard to the function of the locus being converted, or provide guidance as to how such a

conversion might affect the genetic, morphological, and/or physiological characteristics of the claimed invention. Applicants respectfully submit that the function of such a locus is not relevant to the patentability of the claims, except insofar as it may affect the claimed characteristics. Thus one of skill in the art may routinely analyze a soybean plant of claim 10, comprising a single locus conversion, for its elite agronomic and protein, oil, and yield characteristics. Further, the term "single locus conversion" is defined, for example, in the specification at page 11, lines 9-11 and at page 25, lines 7-12. It is routine in the art to screen for and identify a single locus conversion by well known classical and/or molecular plant breeding techniques.

(4) Regarding claims 15-18, and 23-32, the Action alleges that no guidance is provided regarding other soybean plants used in a cross to produce the claimed invention, and that undue experimentation would be required to produce and screen soybean plants to determine which possess the claimed characteristics. Applicants respectfully traverse, in that such experimentation is not undue, but merely represents a routine level of experimentation in the art, and is within the level of one of ordinary skill in the art, depending for instance, on the agronomic characteristics that are desired. First, examples of such varieties to be used in a cross are provided in the working examples. Additionally, the pending claims do not anywhere require that the "same variety" be reproduced following crossing and evaluation of progeny. Instead, the claims define a readily understandable and routinely measurable set of characteristics based on yield, oil, protein levels, and elite agronomic characteristics, allowing for identification of soybean plants in accordance with the claims. One of skill in the art would merely need to follow the working examples to prepare such plants. In view of these arguments, Applicants respectfully request removal of this rejection.

E. Claim rejection under 35 U.S.C. § 102(b)

The Action rejects claims 1-14 and 16-29 under 35 U.S.C. § 102(b) as being anticipated by Cober *et al.* (*Crop Sci.* 40:39-42, 2000), or alternatively by Wilcox (*Crop Sci.* 38:900, 1998). Applicants note that the claims have been amended, and traverse in part.

Regarding the specific lines cited from the Cober reference, Applicants note that none of these lines are described as having an oil content of at least 20%, as now claimed. Further, “elite” agronomic characteristics are not described. The materials and methods section, at pages 39-40, states that initial selections were “randomly taken” and subsequently made on the basis only of protein level. No agronomic characteristics were reported by Cober other than yield, maturity date, and oil and protein content; thus these lines would not be considered “elite.” In contrast, the claimed lines are selected as described in the specification, on the basis of, for instance, lodging resistance, emergence, vigor, and disease tolerance. Further, the single cross lines of Cober that are cited in the action do not demonstrate significantly improved oil content from their low oil parent/high protein parent, while many demonstrate lower yield than that parent. Thus these cited lines are clearly, at best, in the initial stages of breeding and far from being selected as the basis for subsequent breeding use, let alone being elite agronomic lines themselves. One of skill in the art would thus understand that these are not “elite” varieties, but are instead, at most, the basis for further breeding experiments. Thus the cited varieties are distinct from the claimed soybean varieties in terms of oil content and the agronomic characteristics described in the specification.

Regarding Wilcox, Applicants note that the described varieties C1944 and C1945 are not elite varieties, and do not display an oil content of at least 20% as now claimed, but are instead breeding lines stated to be “useful” to “contribute to the development of new breeding lines or cultivars.” The reference describes C1944 as an F₄-derived line that was only tested at a single

location with limited replication and for only two years. The reference describes material later designated as C1945 as having been tested for three years at a single location, and does not describe agronomic characteristics such as disease resistance, or nematode resistance. The present specification defines "agronomically elite" at page 38, lines 8-11, as a genotype displaying distinguishable traits including emergence, disease resistance, vigor, etc. The Wilcox lines do not meet all of the limitations of the claims, and thus do not anticipate the present claims.

In particular, it would have also been unclear to one of skill in the art that the reported beneficial oil, protein and yield characteristics of C1944 and C1945 would have been maintained or improved through each additional generation of a breeding process. In fact, SN30003 and SN300017 (*i.e.* C1944 and C1945) were parental lines for the soybean lines described in the examples, after crosses to elite soybean lines and several further generations of selection for oil and protein content, yield, and overall agronomic performance. However, until the described varieties were in fact obtained, it could not have been predicted that such lines displaying elite characteristics and improved oil, protein and yield characteristics, could be obtained. Thus, removal of the rejection is respectfully requested.

F. Claim rejection under 35 U.S.C. § 102(b) or alternatively 35 U.S.C. § 103(a)

The Action rejects claims 15-32 under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) as obvious over Wilcox *et al.* (*Crop Sci.* 35:1036-1041, 1995).

Regarding claim 15, Applicants respectfully submit that strains CX1038-14 and CX-1307-205 are non-elite, while neither Cutler 71 nor Hamilton display total protein plus oil content of between 64-70%. The data that is provided by Wilcox and Cavins (*e.g.* Table 1) instead indicate that simultaneous maintenance of yield, protein, and oil content of each of the

parental lines was not achieved in the reported progeny lines. In view of this and the amendment to the claims, Applicants respectfully submit that the rejection is moot, and request that it be withdrawn.

Regarding claims 30-32, although the reference states in the abstract that "high seed protein can be backcrossed...suggesting the absence of physiological barriers to combining high seed protein with high yield", as noted by the Action, the reference does not however state the same with respect to selection for oil content in the context of seed yield and protein content, and the "trend" noted for increased oil content in backcross generations appears incorrect, in that the BC1 and BC3 lines do not significantly differ with respect to their oil content. Thus the reference does not provide one of skill in the art with an expectation of success in attempting to create the claimed soybean varieties.

Regarding claims 16-29, the same arguments apply, in that Wilcox's teachings, and any expectation of success in using them, do not extend to the further step of also maintaining or incorporating improved oil levels in a soybean cultivar. As noted above, the data of Table 1 demonstrate that selection to identify progeny simultaneously displaying the parental lines' desired characteristics of yield, protein, and oil content did not succeed to the degree demonstrated by the presently described lines. As shown in Table 1, despite 3 backcross generations to the Cutler 71 high oil parent, oil content showed no trend of improvement between the progeny BC1 and BC3 generations, and remained well below that of the Cutler 71 parent. The cited reference thus does not anticipate or render obvious these claims, and its removal is respectfully requested.

G. Claim rejection under 35 U.S.C. § 103(a)

Claims 15 and 30-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilcox (1998) in view of Conway (U.S. Patent 6,140,556). Applicants respectfully traverse. Applicants disagree with the assertion that Wilcox "teaches an agronomically elite soybean plant, namely C1944...". This line is a breeding line, specifically described as being useful for further breeding, and is not itself an elite line or variety. Wilcox also teaches that the line is useful for "increasing seed protein while minimizing reductions in seed oil content", contrary to the assertion in the action that it is useful to "minimize seed oil content", which appears unclear and may be due to a typographic error. Conway apparently teaches that soybean plants may be crossed to yield novel soybean plants. These references therefore do not motivate one to attempt, nor do they allow one of skill in the art to arrive at, the claimed plants, except perhaps by hindsight. At best they may be viewed as an invitation to try such an experiment, and do not convey a reasonable expectation of success. Indeed, given the previously reported results of Wilcox (as cited in the Action in the Wilcox and Cavins, 1995 reference), one of skill in the art would have found it likely that plants displaying the presently claimed yield, protein, and oil content characteristics would not be obtained. In view of this, removal of the rejection is respectfully requested.

H. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

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The Examiner is invited to contact the undersigned attorney at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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